Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Pharmacovigilance in clinical trials

Changes to safety notifications by Regulation (EU) 536/2014 OR

All SUSARs are intended to be reported directly to the EudraVigilance Database (EVCTM), regardless of whether the study is conducted under EU Regulation 536/2014 or Directive 2001/20/EC.

If the clinical trial continues to run under Directive 2001/20/EC, the reporting requirements according to CT-3 must be complied with. This also means that a request from the sponsor for exemption from the obligation to report serious side effects according to AMG must be sent to the BASG in advance.

Formulate

docx Form: SUSAR request (F_I437) | 62KB
Application for exemption from the obligation to report serious side effects according to § 41e AMG as amended.
11.12.2019

Reporting obligations during the implementation of the clinical trial

Reporting Obligations

The notification obligations of the sponsor are divided into those that have to be made immediately and those that have to be made annually.

Sponsor's prompt notification obligations include:

- Notification of any suspected unexpected serious side effect (SUSAR) that occurred **in the course of the same clinical trial in Germany or abroad** and that resulted in death or is life-threatening within **7 days** of becoming known (§ 41e Para.1 AMG idgF) ,
- Notification of any other presumed unexpected serious side effect that occurred **in the context of the same clinical trial in Germany or abroad** within **15 days** of becoming known (§ 41e Abs.2 AMG idgF)

SUSARs

The concept of a suspected unexpected serious adverse reaction (SUSAR) is of central importance for the immediate notification obligations of the sponsor.

The definition results from the linking of the definitions

- serious adverse reaction (adverse reaction that causes death, is life-threatening, requires or prolongs hospitalization, results in permanent or serious disability or disability, causes congenital anomalies or birth defects) and
- Unexpected side effect (side effect that does not correspond in type or severity with the available information on the investigational medicinal product).

SUSARs are only reported to the BASG indirectly to the EudraVigilance (EV) database (CTMD).

Prerequisite for this notification is a one-time application by the sponsor to the BASG for exemption from the obligation to report serious side effects according to §41e AMG (see below). The transmission of SUSAR reports after the “exemption from the reporting obligation” has been granted is then sent directly to the EudraVigilance (EV) database (CTMD) and not to the BASG as the national authority. The confirmation of receipt for electronic SUSARS is also provided by the EV database and not by the BASG.

Annual Safety Reports (ASR, DSUR)

In addition to the immediate notification obligations, the sponsor must submit an annual report in accordance with Section 41e Paragraph 3 AMG as amended for the duration of the clinical trial, which is to be submitted in accordance with guideline CT-3 of the European Commission in the format in accordance with guideline ICH Topic E2F "Development Safety Update Report (DSUR)" is to be created.

For further details, reference is made to section 8 of the CT-3 guideline and to the BASG FAQ on this topic.

Query notice
Susar@basg.gv.at

Last change on: 06/23/2022